

FAIRFAX COUNTY, VIRGINIA BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement, hereinafter referred to as the "Agreement", is made effective the **[Insert Date]** of **[Insert Month]**, **[Insert Year]**, by and between Fairfax County, Virginia, hereinafter referred to as the "Covered Entity", and **[Insert Name of Business Associate/Contractor]**, hereinafter referred to as the "Business Associate," individually a "Party" and collectively the "Parties".

WITNESSETH:

WHEREAS, The Secretary of Health and Human Services has issued regulations to protect the security, confidentiality and integrity of health information within the Health Insurance Portability and Accountability Act (HIPAA) of 1996, Public Law 104-191, Privacy Rule at 45 CFR Parts 160 and 164; and

WHEREAS, the Parties wish to enter into or have entered into an arrangement whereby [Insert Name of Business Associate/Contractor] will provide certain services to Fairfax County, and pursuant to such arrangement, [Insert Name of Business Associate/ Contractor] shall be considered a "Business Associate" of Fairfax County as defined in the HIPAA Privacy Rule (the agreement evidencing such arrangement is [Insert name of Contract or Work Order], [Contract # or Purchase Order #], dated [Insert date of Contract or PO], and is hereby referred to as the "Arrangement Agreement"); and

WHEREAS, Fairfax County is a single legal entity that is a "Covered Entity" and has designated itself as a "Hybrid Entity" with the **[Insert Agency]** as a "health care component" within Fairfax County's "Hybrid Entity" as those terms are defined in the HIPAA implementing regulations, 45 CFR Part 160 and Part 164 (Privacy Rule); and

WHEREAS, [Insert Name of Business Associate/ Contractor] in the performance of the services of the arrangement, as either a recipient of Protected Health Information (as defined in 45 CFR §164.501) from Fairfax County or has been given access by Fairfax County to Protected Health Information of which Fairfax County has responsibility pursuant to the Privacy Rule or other applicable law, is a "Business Associate" as that term is defined in the Privacy Rule; and

WHEREAS, pursuant to the Privacy Rule, all Business Associates of Covered Entities, including Fairfax County, must agree in writing to certain mandatory provisions regarding the Use and Disclosures of Protected Health Information (as the terms "use" and "disclosure" are defined in the Privacy Rule); and

WHEREAS, the purpose of this Agreement is to comply with the requirements of the Privacy Rule, including, but not limited to, the Business Associate contract requirements at 45 CFR § 164.504(e);

THEREFORE, in consideration of the Parties' continuing obligations under the Arrangement Agreement, compliance with the Privacy Rule, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree to the provisions of this Agreement in order to address the requirements of the Privacy Rule and to protect the interests of both Parties.

1. DEFINITIONS

Except as otherwise defined herein, any and all capitalized terms in this Section shall have the same meaning as the definitions set forth in the Privacy Rule. Such definitions are provided herein for convenience only. Moreover, notwithstanding anything contained herein to the contrary, should the Privacy Rule be further modified, amended or otherwise changed, the definitions of such terms as contained in the Privacy Rule as so modified, amended or changed, shall govern and replace such definitions contained in this Agreement.

- a. "Business Associate" shall mean [Insert Name of Business Associate/Contractor]. In the event that the Business Associate is otherwise a covered entity under the Privacy Rule, that entity may appropriately designate a health care component of the entity as the Business Associate for purposes of this Agreement.
- b. "Compliance Manager" shall mean the designated HIPAA Privacy Official within Fairfax County Government with authority to act on behalf of the Covered Entity regarding all matters related to Fairfax County's compliance with the provisions of the Health Insurance Portability and Accountability Act of 1996.
- c. "Covered Entity" shall mean Fairfax County, Virginia government including the [Insert Agency], as a designated health care component, which shall have authority to act on behalf of the Covered Entity within the terms of this agreement.
- d. "Designated Record Set" shall have the same meaning as the term "designated record set" in 45 CFR §164.501 such that 'Designated Record Set" means: (1) A group of records maintained by or for a covered entity that is: (i) the medical records and billing records about individuals maintained by or for a covered health care provider; (ii) the enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or (iii) used, in whole or in part, by or for the covered entity to make decisions about individuals; (2) For purposes of this paragraph, the term record means any item, collection, or grouping of information that includes protected health information and is maintained, collected, used, or disseminated by or for a covered entity.
- e. "Disclosure" shall have the same meaning as the term "disclosure" in 45 CFR §164.501 such that "Disclosure" means the release, transfer, provision of access to, or divulging in any other manner of information outside the entity holding the information.
- f. "Electronic Media" shall have the same meaning as the term "electronic media" in 45 CFR §162.103 such that "Electronic Media" means (1) Electronic storage media including memory devices in computers (hard drives) and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card; or (2) Transmission media used to exchange information already in electronic storage media. Transmission media includes, for example, the internet (wide-open), extranet (using internet technology to link a business with information accessible only to collaborating parties), leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media, because the information being exchanged did not exist in electronic form before the transmission.
- g. "Health Information" shall have the same meaning as the term "health information" in 45 CFR §160.103 such that "Health Information" means any information, whether oral or recorded in any form or medium, that: (1) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.
- h. "Individual" shall have the same meaning as the term "individual" in 45 CFR §164.501 and shall include a person who qualifies as a personal representative in accordance with 45 CFR §164.502(g) such that "Individual" means the person who is the subject of protected health information and includes a person who qualifies as a personal representative under applicable state and federal law.
- i. "Individually identifiable health information" shall have the same meaning as the term "Individually identifiable health information" in 45 CFR §160.103 such that "Individually identifiable health information" is information that is a subset of health information, including demographic information collected from an individual, and: (i) Is created or received by a health care provider, including Fairfax County, health plan, employer, or health care clearinghouse; and (ii) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; and

- (a) That identifies the individual; or (b) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.
- j. "Privacy Rule" shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 CFR Part 160 and Part 164, subparts A and E.
- k. "Protected health information" (PHI) shall have the same meaning as the term "Protected health information" in 45 CFR §164.501, limited to the information created or received by the Business Associate from or on behalf of Fairfax County such that "Protected health information" means individually identifiable health information that is (i) Transmitted by electronic media; (ii) Maintained in any medium described in the definition of electronic media; or (iii) Transmitted or maintained in any other form or medium. "Protected health information" does not mean individually identifiable health information in: (i) Education records covered by the Family Educational Right and Privacy Act, as amended, 20 U.S.C. 1232g; (ii) Records described at 20 U.S.C. 1232g(a)(4)(B)(iv); and (iii) Employment records held by a covered entity in its role as an employer.
- I. "Required by Law" shall have the same meaning as the term "Required by law" in 45 CFR §164.501 such that "Required by law" means a mandate contained in law that compels an entity to make a use or disclosure of protected health information and that is enforceable in a court of law. Required by law includes, but is not limited to, court orders and court-ordered warrants; subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.
- m. "Secretary" shall mean the Secretary of the U.S. Department of Health and Human Services or his designee.
- n. "Security Rule" shall mean the Standards for the Protection of Electronic Protected Health Information at 45 CFR Part 160 and Part 164, subparts A and C.
- o. "Use" shall have the same meaning as the term "use" in 45 CFR §164.501 such that "use" means, with respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information.
- p. All other terms used in this Agreement have the same meaning as those terms in the Privacy Rule.

2. CONFIDENTIALITY REQUIREMENTS OF BUSINESS ASSOCIATE

- a. Business Associate agrees to use or disclose Protected Health Information only as permitted or required by this Agreement, the Arrangement Agreement, or as required by law.
- b. Business Associate agrees to ensure that its agents, including a subcontractor, to whom it provides Protected Health Information received from, or created or received by Business Associate on behalf of Fairfax County, agrees, in writing, to the same restrictions and conditions that apply through this Agreement to the Business Associate with respect to such information.
- c. Business Associate agrees to take reasonable steps to ensure that its employees' actions or omissions do not cause Business Associate to breach the terms of this Agreement.
- d. Business Associate agrees to use appropriate safeguards to prevent use or disclosure of the Protected Health Information other than as provided for by this Agreement.
- e. Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of Protected Health Information by Business Associate in violation of the requirements of this Agreement.

- f. Business Associate agrees to report to Fairfax County, in writing, any use and/or disclosure of the Protected Health Information that is not permitted or required by this Agreement of which Business Associate becomes aware within ten (10) days of the Business Associate's discovery of such unauthorized use and/or disclosure. The Business Associate shall submit the written report to the Fairfax County HIPAA Compliance Manager.
- g. Business Associate agrees to disclose to its subcontractors, agents or other third parties, and request from the Covered Entity, only the minimum Protected Health Information necessary to perform or fulfill the specific services required or permitted hereunder.
- h. Effective April 21, 2005, the Business Associate agrees as thereafter set forth in the regulations to implement administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the electronic Protected Health Information that it creates, receives, maintains, or transmits on behalf of Fairfax County pursuant to the Security Rule.

3. AUDITS OF BUSINESS ASSOCIATE

- a. Business Associate agrees to permit the Secretary to audit Business Associate's records and practices related to use and disclosure of Protected Health Information to ensure Covered Entity's compliance with the terms of the HIPAA Privacy Rule.
- b. Business Associate shall maintain books, records, agreements, policies and procedures relating to the use and/or disclosure of Protected Health Information in support of the services provided. Fairfax County or its authorized representative shall have the right to audit the books, records, agreements, policies and procedures of the Business Associate under the following conditions:
 - i. If the Arrangement Agreement is terminated for any reason in accordance with the provisions of this Agreement in order to ensure the confidentiality of the protected health information:
 - ii. In the event of a disagreement between the Business Associate and Fairfax County on the amount due the Business Associate under the terms of the Arrangement Agreement;
 - To check or substantiate any amounts invoiced or paid which are required to reflect the costs of services, or the Business Associate's efficiency or effectiveness under this Agreement; and,
 - iv. If it becomes necessary to determine Fairfax County's rights and the Business Associate's obligations under the Agreement or to ascertain facts relative to any claim against the Business Associate that may result in a complaint against the Covered Entity.
- c. These provisions for an audit shall give Fairfax County unlimited access during normal working hours to the Business Associate's books, records, agreements, policies and procedures under the conditions stated above.
- d. Unless otherwise provided by applicable statute, the Business Associate, from the effective date of final payment or termination of the Arrangement Agreement hereunder, shall preserve and make available to Fairfax County for a period of six (6) years thereafter, at all reasonable times at the office of the Business Associate but without direct charge to Fairfax County, all its books, records documents and other evidence bearing on the costs and expenses of the services relating to the work hereunder.
- e. Fairfax County's right to audit and the preservation of records shall terminate at the end of six (6) years as stated herein. The Business Associate shall include this "Right of Audit and Preservation of Records" clause in all subcontracts issued by it and they shall require same to be inserted by all lower tier subcontractors in their subcontracts, for any portion of the work.
- f. Should the Business Associate fail to include this clause in any such contract or lower tier contract, or otherwise fail to insure Fairfax County's rights hereunder, the Business Associate shall be liable to Fairfax County for all reasonable costs, expenses and attorney's fees which Fairfax County may have to

incur in order to obtain an audit or inspection of, or the restoration of records which would have otherwise been available to Fairfax County from said persons under this clause. Such audit may be conducted by Fairfax County or its authorized representative.

4. AVAILABILITY OF PROTECTED HEALTH INFORMATION

- a. Business Associate agrees to provide access, at the request of Fairfax County, to Protected Health Information in a designated record set to Covered Entity, or as directed by the Covered Entity, to an individual, in a time and manner sufficient to permit Covered Entity to comply with the requirements of 45 CFR §164.524.
- b. Business Associate agrees to, at the request of Fairfax County or an individual, make any amendment(s) to protected health information in a designated record set that are directed by or agreed to by Covered Entity, in a time and manner sufficient to permit Covered Entity to comply with the requirements of 45 CFR §164.526.
- c. Business Associate agrees to document disclosures of protected health information and information related to such disclosures (including, but not limited to, the date made, the name of the person or organization receiving the PHI, the recipient's address, if known, a description of the PHI disclosed, and a reason for the disclosure) in a manner sufficient to permit Fairfax County to respond to a request by an individual for an accounting of disclosures of protected health information in accordance with 45 CFR §164.528 and provide such documentation to Covered Entity or an individual as directed by Covered Entity.

PERMITTED USES AND DISCLOSURES BY BUSINESS ASSOCIATE

- a. Pursuant to the above noted Arrangement Agreement, Business Associate provides services ("Services") for Fairfax County and directly or indirectly to individual consumers that involve the use and disclosure of Protected Health Information. Except as otherwise limited in this Agreement, the Business Associate may make any and all uses of Protected Health Information necessary to perform its Services for, or on behalf of Fairfax County as specified in the Arrangement Agreement, provided that such use and/or disclosure would not violate the HIPAA Privacy Rule if done by Fairfax County or the minimum necessary policies and procedures of the Covered Entity.
- b. Business Associate may use the Protected Health Information in its possession for its proper management and administration and to fulfill any present or future legal responsibilities of the Business Associate provided that as to any such disclosure, the following requirements are met:
 - i. The disclosure is required by law; or
 - ii. Business Associate obtains reasonable assurances from the third party to whom the information is disclosed that it will remain confidential and used or further disclosed only as Required By Law or for the purpose for which it was disclosed to the third party, and the third party notifies the Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached.
- c. Business Associate may use and disclose protected health information for data aggregation services provided that the purpose of such aggregation is to provide Fairfax County with data analyses relating to the Health Care Operations of the Covered Entity. The Business Associate may not disclose Protected Health Information of one Covered Entity to another Covered Entity absent the explicit authorization of Fairfax County.
- d. Except as otherwise limited in this Agreement, Business Associate may de-identify any and all Protected Health Information provided that the de-identification conforms to the requirements of 45 CFR §164.514(b).
- e. Business Associate may use Protected Health Information to report violations of law to appropriate Federal and State authorities, consistent with the Privacy Rule.

6. OBLIGATIONS OF COVERED ENTITY

- a. Covered Entity shall notify Business Associate within reasonable time of any limitation(s) in the Covered Entity's Notice of Privacy Practices to the extent that such limitation may affect Business Associate's use or disclosure of Protected Health Information, and provide Business Associate a copy of the current Notice of Privacy Practices.
- b. Covered Entity shall notify Business Associate of any changes in, or revocation of, permission by Individual to use or disclose Protected Health Information to the extent that such changes may affect Business Associate's use or disclosure of Protected Health Information.
- c. Covered Entity has obtained, and will obtain, from Individuals consents, authorizations, or other permissions necessary or required by laws applicable to Fairfax County for Business Associate and Covered Entity to fulfill their mutual obligations under this Agreement.

7. TERM AND TERMINATION

- a. Term: This Agreement shall be effective as of [Insert Effective Date], and shall terminate when the Arrangement Agreement terminates or as provided by Fairfax County's right to terminate the Agreement for cause (paragraph 7.b.).
- b. Termination for cause: Upon the Covered Entity's knowledge of a material breach by Business Associate, Fairfax County at its sole decision shall either:
 - i. Provide an opportunity for Business Associate to cure the breach or end the violation or, if Business Associate does not cure the breach or end the violation within the time specified by Covered Entity, terminate this Agreement and the Arrangement Agreement; or
 - ii. Immediately terminate this Agreement and the Arrangement Agreement if Business Associate has breached a material term of this Agreement and cure is not possible.
- c. Return or destruction of Protected Health Information: At termination of this Agreement, the Arrangement Agreement or upon request of Covered Entity, whichever occurs first, Business Associate shall:
 - i. If feasible, return or destroy all Protected Health Information received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity that Business Associate maintains in any form. Business Associate shall only destroy Protected Health Information with the written approval of Covered Entity. This provision shall apply to Protected Health Information that is in the possession of agents of Business Associate. After return or destruction, Business Associate and its agents shall retain no copies of such information.
 - ii. If return or destruction is not feasible, the Business Associate will provide the Covered Entity with documentation explaining the reasons that it is not feasible. If the Protected Health Information is not returned or destroyed, Business Associate further agrees to extend the protections of this Agreement to the information and limit any further uses and disclosures to those purposes that make the return or destruction of the information not feasible.
- d. Survival: The obligations of the Business Associate under this Agreement shall survive the expiration, termination, or cancellation of this Agreement, the Arrangement Agreement and/or the business relationship of the parties, and shall continue to bind Business Associate, its agents, employees, contractors, successors, and assigns as set forth herein.

8. MISCELLANEOUS

a. **Ambiguity.** Any ambiguity in this Agreement shall be resolved to permit Fairfax County to comply with the HIPAA Privacy Rule.

- b. **Privacy Rule Reference.** A reference in this Agreement to a section in the Privacy Rule means the section as in effect or as amended.
- c. Security Rule Reference. A reference in this Agreement to a section in the Security Rule means the section as in effect or as amended.
- d. Entire Agreement. Unless there is an Underlying Agreement, which Underlying Agreement has been specifically incorporated by reference herein, this Agreement sets forth all of the promises, agreements, covenants, conditions, and understandings between the parties respecting the subject matter hereof and supercedes all prior and contemporaneous negotiations, conversations, discussions, correspondence, memoranda, and agreements between the parties concerning such subject.
- e. **Control.** Notwithstanding 8. d. above, in the event of an inconsistency between the provisions of this Agreement, including definitions, and:
 - i. Mandatory provisions of the HIPAA Privacy Rule, as amended, the HIPAA Privacy Rule shall control. Where provisions of this agreement are different than those mandated in the HIPAA Privacy Rule, the provisions of this agreement shall control.
 - ii. The documentation of the arrangement pursuant to which Business Associate provides services to Covered Entity contains provisions relating to the use or disclosure of protected health information that are more restrictive than the provisions of this Agreement, the provisions of the more restrictive documentation will control.
- f. **Third Party Beneficiaries**. Except as expressly stated herein or the HIPAA Privacy Rule, the parties to this Agreement do not intend to create any rights in any third parties.
- g. **Amendments**. This agreement may be amended or modified only in writing signed by the Parties. However, upon the enactment or amendment of any law or regulation affecting the use or disclosure of Protected Health Information, or the publication of any decision of a court of the United States, or of Virginia relating to any such law, or the publication of any interpretive policy or opinion of any governmental agency charged with the enforcement of any such law or regulation, Fairfax County may, by written notice to the Business Associate, amend this Agreement in such manner as Fairfax County determines necessary to comply with such law or regulation. If Business Associate disagrees with any such amendment, it shall so notify Covered Entity in writing within thirty (30) days of Fairfax County's notice. If the parties are unable to agree on an amendment within thirty (30) days thereafter, either of them may terminate this Agreement by written notice to the other.
- h. **Assignments**. No Party may assign its respective rights and obligations under this Agreement without the prior written consent of the other Party.
- i. **Relationships**. None of the provisions of this Agreement are intended to create, nor will they be deemed to create any relationship between the Parties other than that of independent parties contracting with each other solely for the purposes of effecting the provisions of the Agreement and any other agreements between the Parties evidencing their business relationship.
- j. Waivers. No change, waiver or discharge of any liability, or obligation hereunder on any one or more occasions shall be deemed a waiver of performance of any continuing or other obligation, or shall prohibit enforcement of any obligation, on any other occasion.
- k. **Provisions Found to be Invalid or Unenforceable.** In the event that any provision of this Agreement is held by a court of competent jurisdiction to be invalid or unenforceable, the remainder of the provisions of this Agreement will remain in full force and effect.
- I. **Headings.** The headings in this Agreement are for convenience of reference only and shall not define or limit any of the terms or provisions hereof.

- m. Disputes. If any controversy, dispute, or claim arises between the Parties with respect to this Agreement, the Parties shall make good faith efforts to resolve such matters informally.
- n. Legal Defense. In the event of any judicial, administrative, or other legal action commenced against or threatened against Fairfax County in which it is alleged that the County may be liable, in whole or in part, to be in violation of HIPAA, including, but not limited to, the Privacy Rule, the Business Associate agrees to cooperate with Fairfax County in defense against such action, including making available witnesses and documents to the extent permitted by law.
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Virginia without regard to its cor	Agreement shall be governed by the laws of the Commonwealth of of filling the filling of the Commonwealth of the filling that is a support of the County of Fairfax of Virginia.
	en hereunder to a Party shall be made via U.S. Mail or express cour elow, and/or (other than for the delivery of fees) via facsimile to the ted below.
If to Business Associate , to: Attention:	[Insert Name of Business Associate/Vendor] [Insert BA Contact Name] [Insert BA Address 1] [Insert BA Address 2] [Insert BA Address 3] [Insert BA Fax]
If to Covered Entity , to: Attention: Fax:	[Insert Agency] [Insert CE Contact Name] [Insert CE Address 1] [Insert CE Address 2] [Insert CE Address 3] [Insert CE Fax]
cc : Fax:	HIPAA Compliance Manager [Insert Compliance Manager Name] 12000 Government Center Pkwy Suite 527 Fairfax, VA 22035 703-324-3998
	Parties have executed this Agreement as of the day and year written
FAIRFAX COUNTY:	BUSINESS ASSOCIATE:
Ву:	Ву:
[Insert Signature Authority name]	Printed Name:
Title: [Insert Title] [Insert Agency 2] Date:	Title: Date:
Version 04/14/04	